PODIUM SESSION I: EVERYTHING YOU WANTED TO KNOW ABOUT NICE

NI1

THREE YEARS OF NICE SCIENTIFIC ADVICE: COMPREHENSIVE ANALYSIS OF REQUESTS TO THE PROGRAMME

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OBJECTIVES: The NICE Scientific Advice (SA) programme was established in 2009. It provides written advice to pharmaceutical companies and device manufacturers about development plans for their products to ensure they produce relevant evidence for future submission to NICE. Herein we present a detailed analysis of the NICE SA programme over the past three years. **METHODS:** The NICE SA process involves assessment of the manufacturer's briefing book with input from external clinical experts, health economists and methodological experts. Following a face-to-face meeting between the manufacturer, the expert panel and the SA technical team, a formal written report summarising the advice is produced. In addition, NICE SA provides advice alongside the European Medicines Agency (EMA) and other Health Technology Assessment (HTA) agencies. Whilst such collaborations do not include a formal written report, advice is given verbally at joint meetings. Following these meetings, NICE SA provides a commentary on the manufacturer's minutes, clarifying the issues identified from the perspective of NICE. **RESULTS:** To date the programme has successfully completed 52 formal written advice projects. Requests for advice alongside the EMA and other HTA agencies have been steadily increasing with 13 projects completed since 2010. We produced detailed analyses of all requests to the NICE SA programme to date. Specifically, we will report on the types of questions posed in manufacturers' briefing books including questions on health economic evaluation. We will include a breakdown by therapeutic area, frequency of requests by company, type of company, profiles of participants at meetings, and trends over time. **CONCLUSIONS:** We will reflect on how the various models of advice projects differ, how manufacturers can get the most from the process, and how the NICE SA programme is expected to evolve.

NI2

THE USE OF OFF-LABEL COMPARATORS IN NICE APPRAISALS – AN INDIRECT ENDORSEMENT?

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OBJECTIVES: NICE has a remit to compare new interventions to the current standard of care, which could include off-label medication. NICE must also make recommendations for new interventions within their current marketing authorisations. The objective was to assess how frequently NICE request off-label comparators and the implications of this. **METHODS:** The NICE single technology appraisal (STA) final scopes from 2010-12 were reviewed. All STAs in development (as of 13/06/12) that had not been discontinued and had a draft or final scope were also reviewed. Off-label comparators were identified as those that were being used outside their license according to the European Medicines Agency or the Electronic Medicines Compendium. **RESULTS:** Of 54 completed STAs reviewed, the scopes of 14 (25.9%) requested comparison to at least one off-label comparator. Of these, the manufacturer performed this comparison in half of the cases. When the manufacturer did compare to an off-label comparator, the new intervention was recommended in 4 cases. NICE rejected the other 3 cases for not being cost-effective, thereby indirectly recommending the off-label alternative. Where the manufacturer did not perform the comparison, NICE accepted this decision in 6 (85.7%) cases, but for the other case the ERG performed additional analysis and found the new intervention to not be cost-effective when placed ahead of the off-label drug in the treatment sequence. Again, NICE rejected the new intervention, and indirectly endorsed use of the off-label comparator. Of the 73 STAs in development, 15 (20.5%) scopes requested off-label comparators. **CONCLUSIONS:** NICE have rejected new interventions in favour of off-label comparators, and given the significant number of off-label comparators requested in ongoing appraisals they will likely have to face similar issues in the future. If a new intervention can only be recommended within its licence but its comparators can be indirectly recommended off-label, this poses equality questions.

NI3

PATIENT ACCESS SCHEMES IN THE NEW NHS

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OBJECTIVES: Patient Access Schemes (PAS) have become an integral part of the UK pharmaceutical environment. The research seeks to investigate the historical role PAS have played in regard to Health Technology Appraisals (HTAs), how the mechanism interacts with other features of the UK funding environment, such as the Cancer Drugs Fund (CDF), and the PAS strategies employed by pharmaceutical companies to optimise funding recommendations. It also takes a forward look towards any role PAS might have in a value-based pricing system, which is potentially facing the UK from 2014. **METHODS:** We reviewed NICE Technology Appraisals which included a PAS from 2002 up to June 2012. We then extracted the key information and compared and contrasted the advantages/disadvantages of different schemes as time has progressed. **RESULTS:** PAS have shifted from outcome-based schemes to financially-based discounts. It is clear from the results that as PAS have become more integral to the UK HTA environment, an acceptance of confidentiality and a requirement to prove that PAS reduce uncertainty to payers are two major developments. The research also highlights how the CDF may act as a potential disincentive for manufacturers to engage with PAS and provide the NHS with discounts to achieve cost-effectiveness. **CONCLUSIONS:** As there are set opportunities for manufacturers to submit PAS, it is vital that pharmaceutical companies consider a PAS for the purpose of a HTA as early as possible when bringing a new product or indication to market. The CDF, whilst expanding medicine access to patients, may act as a disincentive for pharmaceutical companies to engage with PAS. With a forward look to 2014, PAS are to remain a vital part of the UK HTA and payer environment.

NI4

ANALYSIS OF STAKEHOLDERS INVOLVED IN HTA DECISION MAKING PROCESS IN THE UK

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OBJECTIVES: To identify the level of influence of people involved in health technology assessment (HTA) and drugs' reimbursement in the UK (with an example of Alzheimer's disease) and to gain deeper understanding who these people are and how they are interconnected within complex HTA network. **METHODS:** The information about members of key national UK HTA agencies (NICE, SMC, AWMSG) was extracted from the agencies web-sites, supplemented by information from other sources, and categorized. Next, we analyzed Alzheimer's disease drugs' assessments (ten HTAs of donepezil, reminyl, rivastigmine, and memantine published from 2001 to 2012). The information about people involved in those assessments was extracted and categorized. A scoring algorithm was developed to calculate each person's weight of influence based on a person's involvement in the assessments and a role within HTA agencies and other organizations. Ni3 visual analysis software was applied to the dataset to observe and visualize interconnections. **RESULTS:** We identified a segment of top influential people within the dataset and analyzed their interconnections (involvement in multiple assessments, organizational affiliations). In total 291 people (associated with the agencies or external) were directly or indirectly involved in HTA process. The majority of these people (61%) were clinicians whereas 11% and 17% had economic and policy background respectively. The average score of SMC members' weight of influence was higher than NICE members because SMC members were mostly involved in multiple assessments. One individual was identified as connected to three key HTA agencies. NHS, University of Southampton, University of Glasgow, and NIHR HTA were identified as key organizations indirectly involved in HTA through their members' connections. **CONCLUSIONS:** HTA network is a complex system with many different stakeholders. Zooming into this system at the people level allowed deeper understanding who these people are, how they are interconnected and contribute to reimbursement decision making process.

PODIUM SESSION I: PRICING, ACCESS AND REIMBURSEMENT

PR1

COMPARISON OF CANCER DRUG PRICES IN THE UNITED STATES AND THE UK

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OBJECTIVES: To understand relative price differential for cancer drugs in the United States and the UK. Develop implications for pricing strategy and patient access for cancer drugs. **METHODS:** Ten branded cancer drugs were selected and their prices for similar dose and packaging were compared in the United States and the UK. Prices were analyzed for the end of 2011 and early 2012. Historical exchange rates were used to convert British pounds to US dollars. Relative price discount was calculated for all selected cancer drugs. KOLs and payers were interviewed to understand current and future implications of this price differential. **RESULTS:** The median price discount for selected ten branded cancer drugs in the UK versus the United States was ~50%. The range of discount for 10 branded cancer drugs was 27%-61%. The price discount for oral small molecule drugs was higher than for biologics (55% vs. 45%). Since the UK is one of the few remaining free pricing markets in Europe, other European markets are likely to have even higher discounts relative to the prices in the United States. Due to rising coinsurance of speciality products, US cancer patients bear significantly higher cost than patients in the UK. KOL and payer interviews suggest US pricing trends for cancer drugs are unlikely to be sustained at this level in the future. **CONCLUSIONS:** US cancer drug prices are significantly higher than the prices in the UK. This price differential is unlikely to be sustained in the future.

PR2

GUIDING PRINCIPLES FOR PROVIDING EFFECTIVE ACCESS TO MEDICINES IN EMERGING MARKETS

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Chronic and non-communicable diseases are becoming a major health problem in emerging markets. Access to effective current and pipeline treatments is limited due to the high cost. Financing solutions will take time as these markets grow and develop public and private insurance systems. However, governments are faced with the immediate problem of access to treatments given limited resources. This paper lays out guiding principles for providing effective access to these treatments within the budget constraints faced by these governments. We looked at how mature markets have used HTA and other pricing and market access tools to evaluate, prioritise and provide access to treatments. We analyse IMS data on products launched since 2005 to find that these markets have broadly used three levers to manage access effectively – time to reimbursement, level of access and price. Treatments with high value to the broad population have been provided quick